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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,941	12/29/2004	Masaya Tanaka	0020-5615PUS1	5052

2292 7590 09/29/2010

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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
09/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,941	TANAKA, MASAYA	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6 and 13-17* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4,6 and 13-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed August 12, 2010 and the Request for Continued Examination filed August 13, 2010

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on August 12, 2010 has been entered. As directed by the amendment 16 and 17 have been added. Thus, claims 1-2, 4, 6, and 13-17 are pending in this application.

Election/Restrictions

2. Newly submitted claims 16-17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4, 6 and 13-15, drawn to a carbon dioxide external administration apparatus, classified in class 128, subclass 202.12.

II. Claims 16-17, drawn to a method of transdermal or transmucosal absorption of carbon dioxide by a human, classified in class 128, subclass 204.18.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as clamed can be practiced with a topically applied cosmetic composition, such as that taught by Tanaka (6,689,339) which comprises sodium alginate, and using a bandage having an adhesive around the external areas surrounding the fabric material. The composition of Tanaka applied to a human skin surface and coverer with a bandage would provide a sealing enclosure over the skin and hold carbon dioxide gas therein; and the composition and metabolic activities of the skin would provide a supply of carbon dioxide to the enclosure.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply: the inventions have acquired a separate status in the art in view of their different classification and art recognized divergent subject matter, and the inventions require a different field of search (e.g., searching different classes /subclasses or electronic resources, or employing different search strategies or search queries).

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is

the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4, 6 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339).

Regarding claim 1, Nishino discloses a carbon dioxide external administration device (figure 1) comprising: a sealing enclosure member (1) capable of sealing a body surface from outside air; the sealing enclosure member being capable of holding carbon dioxide gas within a sealed inside space; a supply means (2) for supplying carbon dioxide gas into an inside space of the sealing enclosure member; and
an absorption aid (water) that is provided in the inside space of the sealing enclosure

member, containing a carbon dioxide-dissolving medium (water) for dissolving carbon dioxide gas, and dissolves carbon dioxide gas to assist transdermal or transmucosal absorption of the carbon dioxide. See: [0008-0015] and figure 1.

However, Nishino lacks the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate.

Tanaka et al teaches a carbon dioxide external administration device with a carbon dioxide absorption aid that contains a carbon dioxide dissolving medium in the form of an emulsion or a cream and said emulsion or cream comprising at least an oil or fat, a surfactant and water. See: Tanaka et al., See: col. 2, lines 36 - col. 9, line 57. Tanaka suggests the use of a viscous material containing sodium alginate (throughout disclosure (e.g. col. 2, line 67 and col. 7, lines 43-45)), examples (e.g. examples 1-79, 81-82, 85-99, 102, 104-105, 107, 109-140, 142, 145-175, 177, 180-196, 199-201, 204-208, 216-219, 226-242, 248-265, 271-287, 293-299) and claims (e.g. claims 1, 3, and 9) or propylene glycol alginate (col. 2, line 67 - col. 3, line 1 and col. 7, lines43-45). See: col. 7, lines 43-46, Tables 1-25 and claims 1, 3, and 9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the absorption aid (water) of Nishino, by using an aqueous viscous gel composition as taught by Tanaka with alcohols having high vaporization temperatures and oils and fats in order to provide an absorption aid comprising the specific ingredients suggested by Tanaka, that would provide “improved skin comfort, usability, and the like of the composition by adding a perfume, color material, moisturizer, oily component..." See: Tanaka col. 9, lines 13-50.

Regarding claim 4, Tanaka teaches incorporating carbon dioxide containing viscous compositions into a sheet for topically applying carbon dioxide gas to skin. See: col. 3, line 65 - col. 4, line 3; col. 12, lines 4-33; col. 43, lines 38 - col. 44, line 58.

Regarding claim 6, Nishino discloses a carbon dioxide external administration device with a sealing enclosure member (1 or 11) that is made from a flexible material having a shape holding ability (when inflated), an elastic and flexible material (it expands and contracts as it is inflated) formed into a shower cap or a boot.

Regarding claim 13, Tanaka suggests the use of a viscous material containing sodium carboxymethyl cellulose. See: col. 2, lines 58-59 and Tables 1-4, 7-10, 12-13, 15-25.which show numerous examples with sodium carboxymethyl cellulose.

Regarding claim 14, Tanaka suggests the use of a viscous material containing sodium dihydrogen phosphate. See: col. 3, line 30 and col. 9, lines 6-12.

7. Claim 2 and is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339) and further in view of Westwood (WO 98/173340).

The combined references disclose all the limitations of claim 2, except the carbon dioxide amount indicator being provided separately from the sealing enclosure member.

Westwood teaches a sealing enclosure member (10) with a valve (18) that would expand (open) when carbon dioxide is supplied into the sealing enclosure member (at least at a given pressure) and contracts (closes) when the amount of carbon dioxide decreases (when the pressure falls below the given pressure). See: figures 1-6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a valve, as taught by Westwood, to the boot device disclosed by the combined references, in order to determine when the optimal amount of carbon dioxide pressure is being applied to the user.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al., (JP 07-171189 A) in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339), as applied to claim 1 above, and further in view of Gedouin et al., (6,258,366). Regarding claim 1, Nishino in combination with Tanaka discloses a carbon dioxide external administration device (figure 1) comprising: a sealing enclosure member (1) capable of sealing a body surface from outside air; the sealing enclosure member being capable of holding carbon dioxide gas within a sealed inside space; a supply means (2) for supplying carbon dioxide gas into an inside space of the sealing enclosure member; and an absorption aid (water) that is provided in the inside space of the sealing enclosure member, containing a carbon dioxide-dissolving medium (water) for dissolving carbon dioxide gas, and dissolves carbon dioxide gas to assist transdermal or transmucosal absorption of the carbon dioxide. See: [0008-0015] and figure 1.

However, Nishino in combination lacks the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate but without the composition containing a carbonate.

Gedouin discloses a composition comprising depolymerized sodium alginate and teaches that it is beneficially applied to a user's skin to protect the skin of the wearer

from the harmful effects of atmospheric pollutants. The composition of Gedouin comprises depolymerized sodium alginate without a carbonate, and this composition is taught to protect the skin from harmful pollutants. See: abstract, col. 2, lines 1-8; col. 3, lines 12-22 and claims 1-3, 9, and 20.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the carbon dioxide absorption aid disclosed by the combined references, by using a sodium alginate aqueous composition without a carbonate, as taught by Gedouin, in order to form a device that promotes blood circulation while simultaneously protecting the skin from harmful pollutants.

Response to Arguments

9. Applicant's arguments filed August 12, 2010 have been fully considered but they are not persuasive.

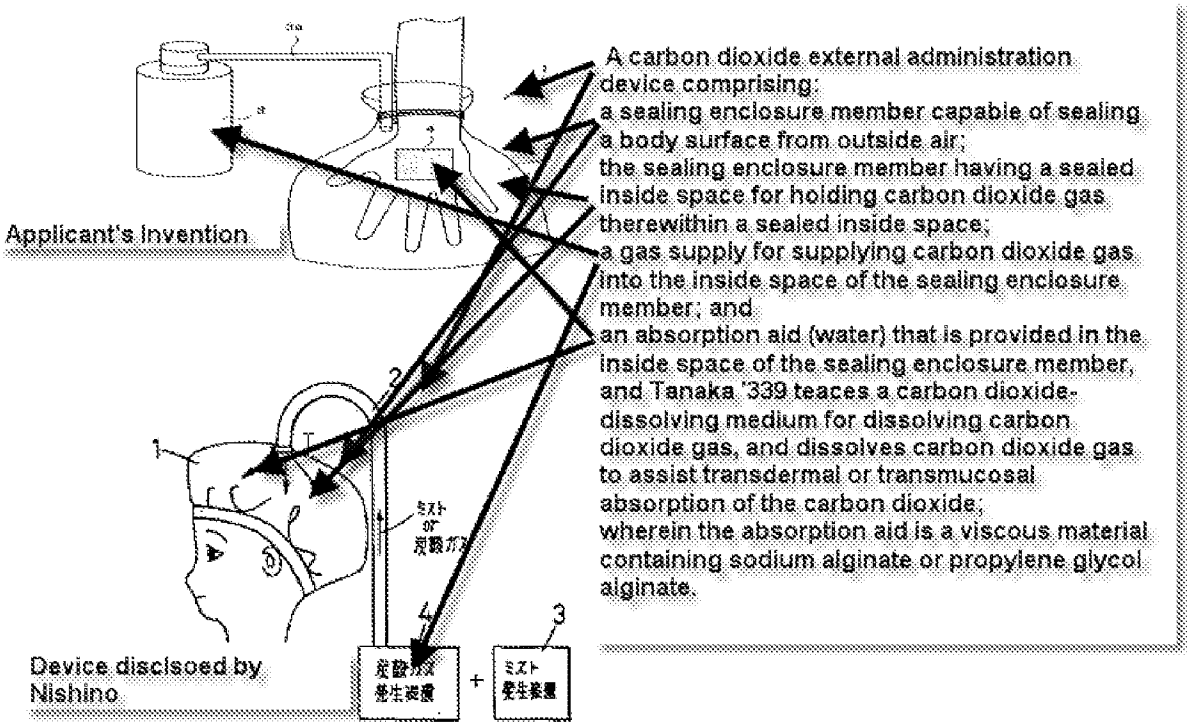
Applicant argues on page 5, third paragraph to page 6, first paragraph that the Masaya Tanaka declaration under 37 CFR 1.132 which compares Example 2 described at pages 25-26 of the present specification against Example 299 of Tanaka (WO 99/24043) provides evidence that the device of Example 2 in accordance with the present invention as compared to Example 299 of Tanaka '339 exhibits advantageously improved skin temperatures which correlates to improved skin moisture content and sebum output properties. The examiner respectfully agrees that the device of Example 2 is shown by the Tanaka declaration to have improved skin temperatures over Example 299 of Tanaka '339.

However, the limitations of Example 2 are not claimed. Example 2 requires numerous embodiments that are not claimed for example, a "viscous material [was] prepared using 1.8 parts by weight of sodium alginate and 1 part by weight of sodium carboxymethyl cellulose as thickeners, 0.2 part by weight of methylparaben as a preservative, and 97 parts by weight of purified water as water, and this viscous material was used as a carbon dioxide absorption aid 4." Moreover, unclaimed modifications including a "plastic glove", a "CO2 cylinder" and a "hand" were used to carry out the experiment, none of which are recited in the rejected claims. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Moreover, the rejection was based upon the combination of Nishino et al., (JP 07-171189 A) and further in view of Tanaka et al., (WO 99/24043, based on the English Equivalent US 6,689,339) and Nishino teaches the device claimed, but lacks the absorption aid as a viscous material containing sodium alginate or propylene glycol alginate. Therefore, to show unexpected results, a comparison of the claimed device, given its broadest reasonable interpretation, should be compared to the device of the combined references. Therefore, the Declaration of Masaya Tanaka has not been

found convincing and the rejections have been MAINTAINED.

FIG. 1



10. Regarding Applicant's argument that on page 6, second and third paragraphs, that Tanaka lacks the sealed enclosure and delivers the gas in bubble form, it should be remembered that Tanaka is the secondary reference and was merely used to teach the specific absorption aid and viscous material containing sodium alginate or propylene glycol alginate. Nishino discloses a device with sealed enclosure with a gas supply for supplying carbon dioxide gas into the inside space of the sealing enclosure member. See: marked up figure shown above.

11. Regarding applicant's argument that both Nishino and Westwood fail to make up for the above-noted deficiencies of Tanaka '339. Applicant is reminded that Nishino is

the primary reference and Tanaka is the secondary reference. Nishino teaches the device claimed including an absorption aid (water) for dissolving carbon dioxide gas, but lacks the specific absorption aid comprising a viscous material containing sodium alginate or propylene glycol alginate. Tanaka teaches a composition for delivering carbon dioxide to the skin of a user comprising the specific absorption aid claimed (i.e. a viscous material containing sodium alginate or propylene glycol alginate).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the absorption aid (water) of Nishino, by using an aqueous viscous gel composition as taught by Tanaka particularly since both inventions are drawn to the delivering carbon dioxide to an external surface of a user.

12. Regarding Westwood, applicant is reminded that Westwood was merely used to teach a carbon dioxide indicator being provided separately from the sealing enclosure, as claimed in claim 2.

13. The examiner concurs with applicant's synopsis on page 7, last paragraph, that Gedouin uses depolymerized sodium alginate to protect the skin against harmful effects of atmosphere pollution and fails to teach components that react together to form carbon dioxide. However, the examiner respectfully disagrees with applicant's argument that since Gedouin lacks the chemical components required by Tanaka '339 and the teaching of employment of any type of carbon dioxide gas; it fails to provide an adequate basis for motivation to one skilled in the art.

First, Nishino teaches the device for administering carbon dioxide to the user. Tanaka clearly demonstrates the safety of using sodium alginate to the external

surfaces of a body and that it can be used to deliver carbon dioxide. The examiner has merely suggested substituting the absorption aid of the combines references with the viscous composition (absorption aid) of Gedouin, which has been show to be useful to deliver carbon dioxide to an external body surface (as taught by Tanaka '339) and would be also beneficially protect the skin from harmful pollutants.

14. Therefore, applicant's arguments have not been found convincing and the rejections have been MAINTAINED.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/KEVIN C. SIRMONS/
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